REMARKS

35 USC §103(a)

The rejection of claims 1-10, 12-16 and 18-21 under 35 U.S.C. §103(a) as being unpatentable over Wheeler (WO 97/32559) in view of the Clariant product brochure has been maintained. The rejection, the text of which is identical to that in the previous office action, states:

> Wheeler teaches the preparation of bi-liquid foam by combining oil-based biliquid foam and an aqueous gel, CARBOPOL gelling polymer and the pH is adjusted to 6.5 with citric acid (page 6, lines 1-10 and 20-23 and example 3).
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> Wheeler teaches cosmetic or pharmaceutical composition comprising a stable dispersion that comprises oil-based bi-liquid foam and an aqueous gel. The oil-based bi-liquid foam of Wheeler is from 1% to 80% by weight of the total formulation. The composition of Wheeler also comprises silicones oils wherein the oils can be cyclomethicone, dimethicone, dimethicone copolyol, lanolin and dimethiconol. Wheeler teaches a formulation further comprising from 0.05% to 0.5% of surfactant and active ingredient in the aqueous or oily phase. Wheeler teaches that the low level of surfactant incorporated into the formulation comprises quaternary ammonium sulfonium salts, amphoteric surfactant, anionic surfactant, alpha-olefin sulfonate, and ester-linked sulfonate. Salts of cross-linked polymers of acrylic acid (carbomers), glyceryl polymethacrylates, or copolymers of polyoxyethylene/polyoxypropylene in mixtures with the previously listed surfactants may serve as gelling agents. Wheeler's composition (example 3) comprises Citric acid at 1% (Example 2) and the composition is adjusted to pH 6.5 (less than pH 7). See page 3, paragraph 2 to page 5 paragraph 2. The 1% of the hydroxyl acid in Example 2 meets the salt requirement in claims 1, 3-5.
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> Regarding the percent amounts of the gallant and the salt, it would be obvious to use appropriate amount of the gallant to effect the desired viscosity of the gelled composition. However, Wheeler does not use polymeric sulfonic acid as a gelling agent. However, Clariant product brochure teaches Aristoflex AVC or copolymer of polyacryldimethyltauramide and vinylformamide gelling agent for aqueous systems and thickening agent for oil-in-water emulsions. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the bi-liquid foam by gelling the composition with CARBOMER polymer according to the teachings of Wheeler. One having ordinary skill in the art would have been motivated to substitute CARBOMER gelling agent with another gelling agent such as polyacryldimethyltauramied-co-viniylformamide (Aristoflex) with the expectation that the aqueous composition will be gelled.

The rejection is again respectfully traversed. Prior to addressing the merits of the rejection, the Applicants wish again to restate the nature of the present invention. The instant invention provides an improved aqueous gel formulation that can be used to deliver the necessary therapeutic agents while retaining the stability and the elegant texture of a gel product. The composition comprises an oil-containing biliquid foam dispersed in a salt-

containing aqueous phase, the aqueous phase having a pH of less than 7 (i.e. acidic) and comprising a polymeric sulfonic acid gellant. The otherwise unstable biliquid foam is stabilized in the presence of the aqueous gel containing the polymeric sulfonic acid gellant and very little surfactant. Unlike known compositions of similar utility, the claimed invention utilizes a polymeric sulfonic acid gelling agent which surprisingly and unexpectedly can be used in the presence of substantial amounts of electrolytes in an aqueous phase having a pH of less than 7 (i.e. an acid pH) without undesirable effects on the texture of the gel.

It is the Examiner's position that Wheeler discloses the Applicants' invention except for the polymeric sulfonic acid gellant. The Examiner relies on the Clariant brochure for the teaching that a polymeric sulfonic acid gellant can be used under low pH conditions to gel formulations of the type disclosed in Wheeler, in an attempt to arrive at the claimed compositions. The Applicants cannot agree with the Examiner that the combination would have been obvious to those skilled in the art. However, given for the sake of argument that the skilled person would have been motivated to substitute the Clariant gellant for the gellant in Wheeler, the hypothetical formulation still would not be equivalent to the Applicants' composition, since the combined teachings of the references would not disclose or suggest a composition comprising an oil-containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase having a pH of less than 7 (i.e. acidic) and comprising a polymeric sulfonic acid gellant, and less than 1% surfactants.

The Applicants acknowledge that Wheeler discloses a composition containing a biliquid foam, the foam containing a very small amount of surfactant, and an aqueous phase having a pH of less than 7. Example 1 of the reference contains less than 1% surfactants – polyoxyethylene lauryl ether and lauryl betaine, and the pH of the aqueous phase is 6.5. Nevertheless, in addition to the lack of any disclosure or suggestion in the reference to use a polymeric sulfonic acid gellant, the reference also fails to disclose or suggest an essential feature of the claimed invention: a formulation comprising a salt-containing aqueous phase having a pH of less than 7, the aqueous phase comprising from about 1 to about 10% salt.

The skin–cleansing product of Example 1 of Wheeler contains no salt. On the other hand, the claimed compositions require salt in the aqueous phase in the range of from about 1 to 10%. As discussed on pages 1 and 2 of the present specification, the problem in the prior art addressed by the present invention is how to formulate a stable, water-based gel-type composition while achieving the maximum efficacy of incorporated actives, particularly oil-soluble actives, and maintaining an aesthetically pleasing, i.e. clear and non-pilling, appearance and an aesthetically appealing, i.e., creamy, texture. The problem is compounded since many

actives can disrupt gel structure, leading to an unstable product with an unacceptable feel on the skin, even moreso when the actives comprise acids, present as electrolytes. Therefore, even were the gellant in the Example 1 formulation of Wheeler replaced with the gellant taught by the Clariant brochure, the resulting formulation would not be the same as the Applicants' compositions, since the resulting formulation would lack the presence of substantial amounts of electrolytes/salts.

Examples 2 and 3 of the reference, also mentioned by the Examiner as having a pH less than 7, disclose conditioning shampoo formulations including 3% NaCl. However, even were the gellant replaced by the gellant taught by Clariant, these formulations also would not meet the limitations of the present claims, which include the presence of less than 1% surfactant. Each of the reference formulations contain over 20 weight percent surfactants, including ammonium lauryl sulphate, ammonium lauryl ether sulphate, cocamidopropyl betaine, coconut diethanolamide and cetostearyl alcohol. The amount of the aqueous ammonium lauryl sulphate alone in each of the example 2 and 3 formulations is 13.5% (.33 x 41). As disclosed in the reference at page 5, line 27 – page 6, line 10, shampoos and shower gels generally contain 4-18% by weight of a primary surfactant and 2-15% by weight of a coactive surfactant. It is disclosed in particular on page 5, lines 7-10 that, "It is clear from the above description that by the nature of the conventional formulations this kind of dispersion contains a higher proportion of surfactant than those previously described as features of the invention." In fact, it is well known that, particularly in shampoos, surfactants are the primary cleansing agent and that surfactants are selected based on proper detergency without degreasing (cleaning without removing too much oil from the hair), ability to form delicate and rich bubbling, easy rinsing, good finish after washing hair, minimal skin/eye irritation, no damage to hair, low toxicity and good biodegradability. Generally, the higher alcohol type-anion surfactant provides the proper detergency and forms rich bubbles, and a non-ionic surfactant is added as coadjuvant. Additionally, the proper balance of surfactants provides a shampoo with a slightly acidic pH of about 5.5 - 6.5, since a basic environment weakens the hair by breaking the disulfide bonds in hair keratin. Citric acid is typically used to provide the desired pH. The cuticle of the hair, which is exposed after the sebum is stripped away, is covered with overlapping scales that are smoothed and soothed in a properly acidic environment. Aggravated scales don't overlap nicely, and they make hair look dull and feel rough. They can also snag other raised scales on neighboring shafts, resulting in snarls. Therefore, the Wheeler reference teaches away from the present invention, since it teaches using substantial amounts of surfactant in the biliquid-containing shampoo formulations having a pH less than 7 and containing substantial amounts of

electrolytes. On the other hand, the Applicants' claims require a composition comprising an oil-containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase comprising 0.01–10% of a polymeric sulfonic acid gellant and having a pH of less than 7, the salt contained in the aqueous phase being present in the composition in an amount of 1-10%, and the composition comprising less than 1% surfactant. That an Applicant acts contrary to the teachings of the prior art is strong evidence of nonobviousness. *In re Hedges*, 228 USPQ 685 (Fed. Cir. 1986).

In contrast to the Examiner's analysis of the teachings of the disclosure in the Clariant brochure, the Applicants submit again that the brochure does not provide any teaching to compensate for the defects of the disclosure of Wheeler as it relates to the presently claimed formulations. The Clariant brochure merely discloses that the polymeric sulfonic acids of the present invention are known in the art for use as a gellant of an aqueous phase of an emulsion, and that the gellant may be used under low pH conditions. Nevertheless, the hypothetical formulations prepared by substituting the polymeric sulfonic acid gellant of Clariant for the conventional gellants disclosed in Wheeler would still not result in the Applicants' claimed compositions, which call for substantial amounts of electrolytes and less than 1% surfactant. As discussed above, one of ordinary skill in the art, reading the disclosure in Wheeler at page 6, lines 7-10 together with examples 2 and 3, would simply not have been motivated to reduce the total amount of surfactants in the low pH shampoo formulations of examples 2 and 3 in Wheeler. Given the state of the art, there would have been no expectation that the Clariant gellant would have successfully gelled the shampoo formulations in Wheeler in the presence of substantial amounts of electrolytes and in the absence of substantial amounts of surfactants.

For the above reasons alone, the rejection of the claims under 35 USC §103(a) cannot stand. However, the Applicants further submit that the surprising and unexpected advantages resulting from the use of the polymeric sulfonic acid to gel the biliquid foam-containing formulations in comparison to the use of the carbomer or other gellants disclosed in Wheeler is neither taught nor suggested by either Wheeler or Clariant. As noted in the present specification at page 3, line 26 – page 4, line 6, the gellants recommended for use in Wheeler perform adequately in non-acidic formulations; however, these gellants are incapable of creating a stable dispersions when the aqueous phase to be gelled contains even low levels of electrolytes or salts of desired active ingredients at an acidic pH. The Applicants have previously submitted two declarations which demonstrate that at pH of less than 7, carbomers, as well as other gellants recommended by Wheeler, do not provide a homogeneous and stable product in the presence of substantial amounts of electrolytes. It is abundantly clear that the ability of the

claimed gelling agents to stabilize an oil-containing biliquid foam dispersed in a salt-containing aqueous phase having an acidic pH of less than 7, in the absence of large quantities of surfactants, could not have been predicted from the cited references. This result is both surprising and unexpected in view of the teachings of the prior art. The unexpected results unequivocally rebut any *prima facie* case of obviousness that may be found in combining the Wheeler and Clariant references. ((*In re Soni*, 54 F.3d 746, 34 USPQ2d 1684 (Fed. Cir. 1995). When an applicant demonstrates substantially improved results, as Soni did here, and states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary.)) Therefore, withdrawal of the rejection of the claims under 35 USC §103(a) is respectfully requested.

Applicants' response to the Examiner's "Response to Arguments"

The Examiner has attempted again, but does not succeed, to restate the Applicants' position. The Applicants' assume that in "a)", the Examiner intended to state that Applicants argue that Wheeler does not disclose or suggest the use of polymeric sulfonic acid gellant. Regarding "b)", the Applicants have stated that while the Matathia and Harrison declarations demonstrate the superiority of the polymeric sulfonic acid in stably gelling compositions containing a biliquid foam, this superiority is both surprising and unexpected.

The Examiner again repeats that Wheeler discloses, in Examples 1, 2 and 3, formulations having a pH of less than 7. The Examiner further calculates that Example 1 has less than 1% surfactant, and states that: "This clearly shows/suggests that the percent surfactant is desired to be less than 1%". The Applicants do not disagree that Example 1 contains surfactant in the claimed range. However, as discussed above, a hypothetical formulation resulting from the combined teachings of Wheeler and Clariant, in which the Wheeler gellant is replaced by the polymeric sulfonic acid gellant, is not equivalent to the claimed compositions which call for the presence of substantial amounts of electrolytes. Example 1 of Wheeler contains no salts.

The Applicants also do not dispute that Examples 2 and 3 of Wheeler disclose shampoo formulations having a pH of less than 7. Nevertheless, as also discussed above, Wheeler clearly states, at page 5, line 27 – page 6, line 10: "...shampoos and shower gels generally contain 4-18% by weight of a primary surfactant and 2-15% by weight of a coactive surfactant". It is further disclosed in Wheeler, in particular on page 5, lines 7-10 that, "It is clear from the above description that by the nature of the conventional formulations this kind of dispersion contains a higher proportion of surfactant than those previously described as features of the

invention." Thus, Wheeler clearly discloses that formulations of the type presented in Examples 2 and 3, having a pH of less than 7 and a significant amount of electrolytes, also require a substantial amount of surfactants (i.e., greater than 20%) to result in a stably gelled biliquid foam-containing composition. On the other hand, the Applicants' compositions are stabilized using less than 1% surfactant.

The Examiner's observations on the Matathia and Harrison declarations, previously submitted by the Applicants, are also inaccurate. The declarations are not submitted merely to show the superiority of using the polymeric sulfonic acid gellant over other gellants such as carbomer, but that the use of the polymeric sulfonic acid effects surprising and unexpected advantages (see, in particular, the Harrison declaration at paragraph 3) over the use of conventional gellants. Although, it may arguably have been obvious to one skilled in the art to try to use of the polymeric sulfonic acid to gel the biliquid-containing composition of Wheeler, it could not have been predicted that the polymeric sulfonic acid would gel the compositions in the presence of substantial amounts of electrolytes and very little surfactant. As discussed in the Matathia declaration, various gellants were tested in developing the formulations of the present invention, including the carbomer, but only the polymeric sulfonic acid gellant produced an aesthetically and commercially acceptable product. As further discussed in the Harrison declaration, two formulations (derived from Wheeler example 5, which does not include surfactants in addition to the surfactants used in the biliquid foam) were compared. The formulations were adjusted to acidic pH and differed only in the type of gellant used. The results demonstrate that only the formulation using the polymeric sulfonic acid gellant retained its integrity. The traditional gellant recommended in Wheeler did not, in the absence of additional surfactants, produce a stable composition at a pH below 7. As illustrated in the declarations, In the presence of substantial amounts of electrolytes and very little surfactant, only the polymeric sulfonic acid gellant produced a commercially and aesthetically acceptable product; that is, a product demonstrating stability under conditions which would induce instability in the Wheeler compositions, and adequate viscosity without lumps or pilling when rubbed out on the skin. For this additional reason, the rejection of the independent claims, 1, 12 and 19, under 35 U.S.C. §103(a) should be withdrawn. Claims 2-10; 13-16, 18; 20 and 21, which depend from and include all of the limitations of the independent claims, are patentable for the same reasons as are their respective independent claims.

Conclusion

Wheeler discloses formulations having a pH of less than 7. Wheeler also discloses compositions containing less than 1% surfactants. Clariant discloses a polymeric sulfonic acid gellant. Nevertheless, neither Wheeler nor Clariant recognizes that an aqueous composition comprising biliquid foam and electrolytes can be stabilized at acidic pH with less than 1% surfactant in the total composition, the stability of the gel being unaffected by acids when polysulfonic acid gellant is employed.

The present claims are believed to be in condition for allowance, and prompt issuance of a Notice of Allowance is respectfully solicited. The Examiner is encouraged to contact the undersigned by telephone if it is believed that discussion will resolve any outstanding issues.

A petition and fee for extension of time for two months is being submitted concurrently with this paper. A Notice of Appeal and the requisite fee also are being submitted concurrently.

Respectfully submitted,

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